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EXAMINER	
BAUSCH, SARAE L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,180	SAWITZKI ET AL.	
	Examiner	Art Unit	
	SARAE BAUSCH, PhD	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-57* is/are pending in the application.

4a) Of the above claim(s) *26-39,47 and 49-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-46, 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/05, 02/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicants correspondence mailed 08/04/2008. The amendment to the claims mailed 08/04/2008 has been entered

Election/Restrictions

2. Applicant's election with traverse of group V in the reply filed on 08/04/2008 is acknowledged. The traversal is on the ground(s) that group V and VI do relate to a single inventive concept, at least because the common inventive concept of claim 40 and the fact that the level of nucleic acid molecule can be indirectly determined by measuring expressed peptide or its activity. This is not found persuasive because the common inventive concept of claim 40 is detection of the level of SEQ ID NO 7, which is a nucleic acid. Thus, detection of a peptide activity or peptide concentration or isoforms concentration is not related to the common inventive concept. Peptide activity, peptide concentration, and isoforms concentrations are structurally and functionally distinct and thus do not share a common inventive concept with level of SEQ ID NO 7 in a sample.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 26-39, 47, 49-57 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/04/2008.

4. Claims 40-46 and 48 are under examination. It is noted that claims 46 and 48 have been amended to depend from claim 45 and 40 and thus are now under examination. Additionally, claim 43 is under examination, as it reads on nucleic acid detection.

Drawings

5. The drawings are acceptable.

Claim Rejections - 35 USC § 112- Enablement

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 40-46 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and the breadth of the claims

The claims are drawn to a method for detection of graft reaction in a sample from a patient by characterizing the level of SEQ ID No 7 in a sample compared to a control level of a comparative sample from a healthy patient wherein the graft reaction or absence thereof is detected by a modified level in the sample compared to control. Additional claims are drawn to graft that is lung, spleen, heart, kidney, liver, pancreas, or tissue (claim 41) or islets, aortas, cartilage (claim 42), as well as level is determined by gene expression, number of copies of nucleic acid, DNA or RNA concentration (claim 43) or mRNA concentration (claim 44). The claims are further limited to rejection crisis, rejection reaction, course of rejection, tolerance reaction, or course of tolerance (claim 45) and is detected by reduced level (claim 46) or increased level (claim 48)of nucleic acid molecule.

The rejected claims encompass analysis of any patient, human and non-human. Claims 40-44 encompass any type of graft reaction, including any type of rejection and tolerance and any increase or decrease level of SEQ ID NO 7 detection. Claims 40, 43-46 and 48 encompass any type of graft.

The nature of the claims requires the knowledge of a correlation between the detection level of SEQ ID No 7 and a graft reaction.

The invention is in a class of inventions which the CAFC has characterized as "the unpredictably arts such as chemistry and biology" (Mycolgen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Federal Circuit 2001)).

Guidance in the Specification

The specification asserts that the invention provides efficient and reliable immune markers which enable a certain and fact prediction of risk of graft rejection or the absence thereof, as a form of tolerance (see pg. 4 lines 22-26). The specification assert that rejections are defined by functional deterioration of organs, however the specification teaches that functional deterioration is not always due to rejection but can be caused by toxicity and infection (see pg. 2 lines 25-30). The specification asserts that detection of graft reaction in a sample from a patient is determined in a sample by a level of a nucleic acid and the level is compared with a control level of a comparative sample from a healthy patient, wherein the graft reaction are detected by a modified level in the sample compared to control level (see pg. 9 lines 5-8). The specification does not provide any guidance on if an increase or decrease level of nucleic acid is predictive of graft reaction in a patient. For example, the specification does not indicate or provide any guidance that an increase or decrease , and how much increase or decrease of SEQ ID NO 7 would be predictive of a rejection or tolerance of a graft in a human or any other organism.

The specification further asserts that graft reaction means any physiological and pathophysiological interaction of the graft with the receptor organism, but also any isolated reaction within the graft. The specification teaches that the graft reaction can be tolerance or a rejection of the graft (see pg. 9 lines 9-30). The specification further defines a patient as an organism that comprises a graft, especially human organism, thus the claims encompass any human or non-human organism that comprises a graft (see pg. 10 lines 11-12) and asserts that graft comprises lung, spleen, heart, liver, pancreases and tissues, islets, aortas, cartilage (See pg. 10 lines 24-26). The specification asserts that modification means that the nucleic acid molecule exhibit detectable changes in their concentration compared to a control level (see pg. 10 lines 19-

23), however the specification does not provide guidance on how much change is required and how this change correlates to graft reaction in any species.

The specification teaches that rejection reaction, course of rejection and rejection crisis is detected by an increased level of nucleic acid (see pg. 12 lines 16-30) and teaches that tolerance and course of tolerance is detected by an increased level of nucleic acid (see pg. 13 lines 13-28). Thus, based on the guidance in the specification it is unpredictable to determine an increased level of SEQ ID NO 7 to determine graft reaction, as both a tolerance and rejection would be indicated by increased levels of SEQ ID NO. 7. Furthermore, SEQ ID NO 7 is a cDNA from a rat (See pg. 17 ex 1). The specification does not indicate nor provide any guidance that this sequence is also present in other organisms, and even if this sequence was present in other organisms, the specification provides no guidance on how the level of this sequence would be indicative of graft reaction in other species.

The specification provides a working example of isolating mononuclear cells from receptor animals treated with control antibodies and isolated cDNA fragments that were expressed at increased levels in grafts of tolerance-developing receptor animals (see pg 17 last para cont'd to page 18, first para). Figure 2 demonstrates the results of expression analysis for T8 (SEQ ID NO 7) for kidney transplantation model in rats. The specification asserts that all cDNA fragments were strongly expressed in permanently accepted grafts but grafts of receptor animals treated with control antibodies, their expression is decreased at the time of rejection (see pg. 18 lines 21-30). However, figure 2 demonstrates that in the first 10 days expression of SEQ ID NO 7 in both rat models is decreased and after ten days the expression level increases above the lowest expression level but this graph does not indicate that SEQ ID NO 7 is strongly

expressed in permanently accepted grafts as both the control and RIB5/2 assayed have decreased expression initially and the expression level in RIB5/2 never exceeds the initial expression level. Thus figure 2 and example 1 does not provide any guidance on how to determine that the expression level of SEQ ID NO 2 is predicative of graft reaction when both the tolerance and rejected models have decreased expression levels.

The specification asserts that figure 3 corresponds to mRNA from heart transplantation model. The specification asserts that mRNA expression is reduced in rejecting receptor animals while the accepted graphs exhibit a high mRNA expression for T8, which is reflected in both the graft and peripheral blood (see pg. 19 lines 1-12). The specification asserts that a strong expression drop of T8 in the periphery in rejecting receptor animals more than 2 days before a clinical manifestation of rejection enables non-invasive diagnostics in the blood (see pg. 20 lines 4-8). However, figure 3 demonstrates that the expression levels of both the rejecting receptor animal and the accepted grafts exhibit the same expression levels (see figure 3, T8). Additionally, the expression level of accepted graft does increase over time however this is not an increase relative to the initial expression level, nor does the graph evaluate the expression level of T8 in the rejecting receptor animal over the entire time period to determine if the increase in expression after 10 days is the same in both models. Additionally, figure 4 demonstrates the expression level in blood and demonstrates that T8 does not increase or decrease in the accepted graft, thus it can not be concluded that an increase level of SEQ ID NO 7 is indicative of accepted graft as neither figure 3 nor figure 4 demonstrate that the expression level of SEQ ID NO 7 increases nor does the specification provide data that is statistically

significant to determine that the increase is predictive. Furthermore, the specification does not teach what is encompassed by an accepted graft in the animal models.

The specification provides a working example of mice which accept allogenic livers spontaneously. The specification asserts that figure 7 summarizes the results and that spontaneous tolerance with transient self-limiting rejection crisis is reflected by a high expression of tolerance markers T8. However, figure 7 only demonstrates expression level of a mouse that accepts allogenic livers spontaneously and demonstrates that the expression level of SEQ ID NO 7 does not change over time for the tolerance, however the figure does not evaluate SEQ ID NO 7 in a control population, such as a rejection group to determine if the expression level is indicative of tolerance.

It is unclear from the lack of guidance in the specification how to determine a graft reaction in any patient by measuring the level of SEQ ID NO 7 to a control sample. The specification only gives limited guidance with respect to working examples of determining expression levels in rat and mouse models of heart, kidney, and liver transplants. The specification does not demonstrate expression levels of SEQ ID NO 7 in any other organ or tissue or in any other patient population other than the rat and mouse models. The specification does not provide guidance on the amount of expression that is predictive of tolerance or rejection of graft. The specification only gives limited guidance with respect to decreases in expression levels in a rat model and a mouse model. Additionally, the specification does not provide any statistical analysis to predictably associate an expression level of SEQ ID NO 7 with graft reaction.

The specification does not teach a predictive value or a connection between the expressed SEQ ID NO 7 and the status of the accepted and rejected grafts. The specification does not provide any guidance with the status of the graft, for example the specification does not evaluate heart function, liver function, or kidney function of the accepted grafts for SEQ ID NO 7 to provide guidance on what constitutes an accepted graph versus a rejected graft. Based on the teachings in the specification, it is unclear how the expression level of SEQ ID NO 7 would determine graft reaction in any patient.

The specification does not provide any guidance of expression levels of SEQ ID NO 7 of grafts in human nor does the specification teach that expression level of SEQ ID NO 7 in grafts of spleen, pancreas, tissue, inslets, aorta, or cartilage much less the reaction of the graft of each of these organs or tissues in any patient population. The specification does not provide any statistically significant expression level data that would predictably determine that the expression level of SEQ ID NO 7, either an increase or decrease, would be associated with a graft reaction. It is unclear how the skilled artisan would be able to determine a graft reaction in a patient because the specification does not teach the level of SEQ Id NO 7 that is correlative to different graft reactions with different types of grafts in different organisms. The specification only demonstrates expression level of SEQ ID NO 7 in rat model and mouse model of heart and kidney graft, as well as liver graft, however the patient population of this study appears to extremely small, consisting of only one rejected graft animal and one accepted graft animal for kidney and heart grafts and only one accepted graft animal for liver grafts were evaluated.

The specification envisions hypothetical situations where expression level of SEQ ID NO 7, both an increase and decrease could determine both a tolerance and a rejected graft reaction in

any patient population. The specification appears to be conceiving of possible scenarios where any expression level of a rat cDNA, SEQ ID NO 7 could be used to determine graft reactions in other species, however it is unclear how one of skill in the art would determine the level of expression necessary to determine if the graft is either rejected or accepted as well as if SEQ ID NO 7 even exists in other species, much less if SEQ ID NO 7 is then expressed in grafts of other species and predictive of graft reactions in these species.

The unpredictability of the art and the state of the prior art

While the state of the art and level of skill in the art with regard to detection of a gene expression is high, the level of unpredictability in associating any particular expression level with a phenotype is even higher. The level of unpredictability is demonstrated by the prior art, the post filing art, and the instant specification.

The prior art does not teach any association between SEQ ID NO 7 and graft reaction. The prior art teaches that there are many parameters that are needed to be evaluated prior to using gene expression as a test to determine graft reaction.

It is unpredictable as to whether or not a sequence comprising SEQ ID NO 7 exists in any human or non-human organisms other than rattus novergicus, and whether or not detection of a SEQ ID NO 7 in any other organism would be predictive of graft reaction. For example, Coleman (DDT, 2003, vol. 8 no. 6, pp. 233-235) analyzes direct comparison of gene expression in mice and humans. Coleman teaches that the basic pattern of gene expression between mice and human differs and that 59% of gene are expressed in all tissues but at greatly differing levels (see pg. 234, 2nd column, last para). Coleman teaches mouse and human gene expression patterns and teaches that not all patterns are similar and that the validity of mouse or other

animal species as a human surrogate should not be assumed and some attempt should be made to establish its suitability, such as comparative gene expression studies (see pg. 235, last para). Additionally, Seddiqi et al. (J Mol Evol (1994), vol. 39, pp. 655-660) teaches comparison of mRNA expression of a gene among different species of Rattus norvergicus, Bos taurus, and Homo sapiens. Seddiqi teaches that the coding sequence of protein h3 between R. norvegicus and H. sapien is 88.5% identical and Bos Taurus and Rattus norvergicus is 94% identical (see pg. 1st column, last para), the expression of the mRNA in different tissues among the different species is vastly different (see figure 3a-c). Therefore, Seddiqi et al. teaches that a H. sapiens protein h3, that is very closely related structurally to both B. Taurus and R. norvegicus has great variability of mRNA level and this mRNA level is dependent on both tissue and species (see pg. 660, 1st column, last para). Thus both Seddiqi and Coleman teach that it is not predictable to determine expression level of a nucleic acid among different species and difference tissues and thus its unpredictable to extrapolate that expression level of one nucleic acid to any tissue and any species, based on expression level of SEQ ID NO 7 in rattus norvegicus. Thus it is entirely unpredictable as to whether or not the level of SEQ ID NO 7 would be associated with graft reaction in any tissue in any species.

Shalon et al. (US 2001/0051344 A1 Dec 13, 2001) teach that due to variations in genetic make-up of unrelated individuals in a heterogeneous society, differences in the expression of a gene between any two individuals may or may not be significant (see page 10, paragraph 0155). Shalon et al. further teach that the larger the number of individuals tested, the more significant the remaining differences in gene expression become and samples from at least 5 and preferably 20-50 different test individuals are assayed to obtain statistically meaningful data showing a

statistical elevation or reduction in report levels when compared to control levels (see page 10, paragraph 0156). Sharlon et al. teach that the test average pattern is compared with a control average pattern on a microarray to identify test genes which show significantly, typically at least 2 fold and up to 100 fold or more, increase or decrease in gene expression level with respect to control levels for the same gene (see page 10, paragraph 0158). Post filing art, Kroese et al. (Genetics in Medicine, vol 6 (2004), p. 475-480) teach genetic tests are heterogeneous in nature and the exact characteristics of a particular genetic test to be evaluated must be tightly defined. Kroese et al. teach that a particular genetic condition may be caused by more than one gene and these variations may be due to deletions and insertions not detected by routine sequence methods. (see page 476, 2nd column, last paragraph). Kroese et al. teach that genetic test is shorthand to describe a test to detect a particular genetic variant for a particular disease in a particular population and for a particular purpose and that it should not be assumed that once the characteristics of a genetic test are evaluated for one of these reasons that the evaluation will hold or be useful for other purposes and all measures of the test performance should be presented with their 95% confidence intervals (see page 477, 1st column, 1st and 2nd full paragraph). Kroese et al. teach that the limitations of our genetic knowledge and technical abilities means that for the moment there are likely to be gaps in the information needed to complete a thorough evaluation of many genetic tests (see page 479, 2nd column, last paragraph).

Furthermore, Ionnidis (Plost Med, 2005, 2(8):e124) teach that most published research findings are false. Ionnidis et al. teach that ill-founded strategy of claiming conclusive research finding solely on the basis of a single study assed by formal statistical significance represented and summarized by p values (see pg. 0696, 2nd column, 1st full para.) Ionnidis et al. teach that

research findings are likely to be true that in fields that undertake large studies, such as randomized controlled trials (several thousand subjects randomized) than in small studies such as sample sizes 100 fold or smaller (see pg. 0697, 3rd column, 2nd full para.) Ionnidis et al. teaches that what matters is the totality of evidence and that statistical significance of a single study only gives a partial picture (see pg. 0701, 1st column). Additionally, Hattersley et al. (Lancet, 2005, vol 366, pp. 1315-1323) teaches that the key quality in an association study is sample size (see page 1318, 2nd column, 1st full paragraph). Hattersley et al. teach that sample sizes of thousands are needed to detect variants that are common but have low relative risk and teach that allelic odds ratio of 1.1 to 2.0 requires the number of controls to be in thousands (see page 1318, 2nd column, 1st full paragraph and table 3). Hattersley et al. teach that apparent studies in identifying interesting associations with studies much smaller than implied by table 3 (in the thousands) might suggest that calculations are too pessimistic and small initial studies rarely find the correct result and even when they do they are likely to overestimate the true effect size (see page 1318, 1st column, 1st full paragraph). Hattersley et al. further teaches that emphasis has been on the need for greater stringency in the association studies in order to prove a given association and suggest a p value of $5x10^{-8}$, however arguments from Bayesian perspective suggest that $5x10^{-5}$ should be sufficient to constrain the false discovery rate.

Therefore, based on the prior art teachings, coupled with the data presented in the specification it is unpredictable to correlate levels of SEQ ID NO 7 with graft reaction in any patient, as the specification does not teach a large sample size, confidence levels greater than 95%, or analysis of SEQ ID NO 7 in other species.

Quantity of Experimentation

Given the lack of guidance in the specification with regard to association of the level SEQ ID NO 7 with a graft reaction in "any" species the quantity of experimentation in this area is extremely large. The skilled artisan would have to perform an extremely large study and include different species populations and expression analysis of SEQ ID NO 7 in different tissue and organ grafts to determine if in fact there was either an association between the expression of SEQ ID NO 7 in a patient and graft reaction. The skilled artisan would have to perform an study of comparative expression analysis of SEQ ID NO 7 in other species in other tissues to determine if SEQ ID NO 7 is expressed comparatively in different tissues, organs, and species and then determine if this expression changes upon graft reaction. The results of such a study are unpredictable as evidence by the post filing art (which reflects the current state of the art) and the teachings in the specification. In the instant case, it would be unpredictable as to whether or not any expression level change of SEQ ID NO 7 would be predictive of a graft reaction in a patient. In order to practice the invention as broadly as it is claimed, the skilled artisan would have to perform an extremely large amount of trial and error analysis in a large study to determine if such expression levels would predictably determine any or all graft reactions. Given the lack of guidance in the specification and the post filing art with respect to accurately testing genetic diseases, such analysis is replete with unpredictable experimentation and is considered undue.

Conclusion

8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Sarae Bausch/
Primary Examiner, Art Unit 1634